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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

12M2/1203

CUSHMAN DARBY AND CUSHMAN
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NINTH FLOOR
WASHINGTON DC 20005-3918

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/491,892	07/14/95	007	BADIO, B	1209 12/03/97
First Named Applicant	HANSEN,	ERIK T.		

TITLE OF INVENTION NEW CRYSTALLINE FORM OF A VITAMIN D ANALOGUE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 218100	514-169.000	U80	UTILITY	NO	\$1320.00	03/03/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as yes, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

- III. All communications regarding this application must give application number and batch number.
Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Notice of Allowability

Application No.

08/491,892

Applicant(s)

Hansen et al.

Examiner

Barbara Badio

Group Art Unit

1209



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to May 13, 1997

☒ The allowed claim(s) is/are 1-5, 7, and 8

☐ The drawings filed on _____ are acceptable.

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

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DETAILED ACTION

Status of the Application

1. The amendment filed May 13, 1997 has been entered.
2. Claims 1-5 and 7-8 are pending.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The declaration recites "the duty to disclose information which is material to the *examination* of this application in accordance with Title 37, Code of Federal Regulations, § 1.56". 37 CFR 1.56 states the disclosure of information which is material to the *patentability* and not to the examination of the application.

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EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Paul Kokulis on November 26, 1997.

5. The application has been amended as follows:

Claims 1 and 7, the phrase "characterized by its storage stability at 40°C" has been changed to ~~characterized by its storage stability at 40°C~~ after 12 months--

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Allowable Subject Matter

6. Claims 1-5 and 7-8 are allowed.

7. The following is an examiner's statement of reasons for allowance:

The rejection under 35 USC 103 over Calverley et al. ('048) in view of Jolly et al. ('325) has been withdrawn in light of applicant's arguments presented in Paper No.8. Applicant argues that Calverley teaches the crystalline anhydrous form of calcipotriol which is difficult to formulate. Applicant also argues that Jolly teaches the hydrated

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form of $1\alpha,25$ -dihydroxycholecalciferol is stable but is silent about the stability of other form of the compound, including the anhydrous form, as well as the temperature at which the hydrated form is stable. Therefore, one of ordinary skill in the art would not be motivated to make the monohydrate of calcipotriol having the properties as claimed in the present invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

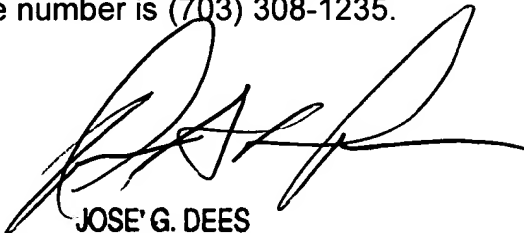
Telephone Inquiry Contacts

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

BB
November 26, 1997


JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
GROUP 1200